

To: Cogliano, Vincent[cogliano.vincent@epa.gov]
Cc: Wood, Charles[Wood.Charles@epa.gov]; Birchfield, Norman[Birchfield.Norman@epa.gov]; Lobdell, Danelle[Lobdell.Danelle@epa.gov]; McQueen, Jacqueline[McQueen.Jacqueline@epa.gov]
From: Flowers, Lynn
Sent: Tue 12/8/2015 9:57:16 PM
Subject: TRY THIS ONE! Glyphosate follow up
Glyphosate Summary of ORD discussion Dec 2015.docx

I got something screwed up and I think it is now fixed. Please ignore last version.

Lynn Flowers, PhD, DABT

Associate Director for Health

National Center for Environmental Assessment

US EPA

Washington, DC

703-347-8537

From: Cogliano, Vincent
Sent: Tuesday, December 08, 2015 4:27 PM
To: Flowers, Lynn <Flowers.Lynn@epa.gov>
Cc: Wood, Charles <Wood.Charles@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>; Lobdell, Danelle <Lobdell.Danelle@epa.gov>; McQueen, Jacqueline <McQueen.Jacqueline@epa.gov>
Subject: Re: Glyphosate follow up

Thanks, Lynn, for the additional text. For completeness, let's add the criteria for "Not likely." It's fundamental to understanding why some of us think a classification of "Not likely" is inappropriate.

Also, if the rationale for "Inadequate" is negative data that are not strong enough for "Not likely," then you've either dismissed the human studies or dichotomized their value to "not causal." The only way I see to get to "Inadequate" is that the positive human data are in conflict with the (largely) negative animal data.

Vince

On Dec 8, 2015, at 15:51, Flowers, Lynn <Flowers.Lynn@epa.gov> wrote:

Ok! I did some significant editing, thinking that what we needed was a complete 2 pager that Tom could provide to OPP based on Kacee's guidance.

I used Vince's draft and the comments from Danelle and Charles.

I have attached a redline but I would just read the clean copy if I were you. It got messy because I added a bunch of additional comments and statements around what Vince provided 😊.

See what you think.

Lynn

Lynn Flowers, PhD, DABT

Associate Director for Health

National Center for Environmental Assessment

US EPA

Washington, DC

703-347-8537

From: Wood, Charles

Sent: Monday, December 07, 2015 5:31 PM

To: Birchfield, Norman <Birchfield.Norman@epa.gov>; Lobdell, Danelle <Lobdell.Danelle@epa.gov>

Cc: Cogliano, Vincent <cogliano.vincent@epa.gov>; McQueen, Jacqueline <McQueen.Jacqueline@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>

Subject: RE: Glyphosate follow up

Hi Norm,

For point 6 (and perhaps 9), I would add 'Inadequate evidence' and 'Not likely to be carcinogenic' at the end to capture full range of opinions.

--Charles

From: Birchfield, Norman
Sent: Monday, December 07, 2015 12:44 PM
To: Wood, Charles <Wood.Charles@epa.gov>; Lobdell, Danelle <Lobdell.Danelle@epa.gov>
Cc: Cogliano, Vincent <cogliano.vincent@epa.gov>; McQueen, Jacqueline <McQueen.Jacqueline@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>
Subject: Fwd: Glyphosate follow up

Hi Charles and Danelle

Vince has summarized the perspectives expressed at our discussion with Tom a couple of weeks ago. Can you take a look and make sure you are okay with how he characterized things? I expect this write up will be transmitted to OPP.

From my perspective I think the write up could be more inclusive of the possibility of "inadequate information" due to conflicting results of studies.

Danelle - in paragraph 4 below, is the word "insisted" good? Would "OPP preferred to dichotomize the data" be better?

Thanks

Norm

Sent from my iPhone

Begin forwarded message:

From: "Cogliano, Vincent" <cogliano.vincent@epa.gov>
Date: December 7, 2015 at 12:01:11 PM EST
To: "Birchfield, Norman" <Birchfield.Norman@epa.gov>
Subject: Re: Glyphosate follow up

Hello Norm—Here are my thoughts on Kacee's second item below (ORD's conclusions under the cancer guidelines). The scientists who reviewed glyphosate materials didn't develop conclusions. If pressed, though, here's what I think might become a joint conclusion. It would be good to circulate this among the ORD scientists to get their views and edits ... Thanks!—Vince

Draft thoughts on glyphosate

1. There are five cancer guideline categories:

- Carcinogenic to humans
- Likely to be carcinogenic to humans
- Suggestive evidence of carcinogenic potential
- Inadequate information to assess carcinogenic potential
- Not likely to be carcinogenic to humans

2. Nobody—including IARC—supports the top category (Carcinogenic).

3. ORD's epidemiologists agree with IARC that there is "limited evidence" of carcinogenicity in humans. Our epidemiologists understand IARC's definition of "limited evidence" as "a positive association has been observed" for which a causal association is "credible, but chance, bias, or confounding could not be ruled out with reasonable confidence [IARC Preamble, section B6]." This positive association would rule out the last EPA category (Not likely to be carcinogenic).

4. At the ORD-only meeting you attended, you heard Danelle say that she tried to communicate this nuanced evaluation of the epidemiology, but that OPP insisted on dichotomizing this to be either "causal" or "not causal." This dichotomization is a major factor in the different positions.

5. Under the EPA's cancer guidelines, "Likely" means that the "weight of the evidence is adequate to demonstrate carcinogenic potential to humans," giving as an example "an agent demonstrating a plausible (but not definitively causal) association between human exposure and cancer, in most cases with some supporting biological, experimental evidence, though not necessarily carcinogenicity data from animal experiments."

6. I believe that ORD scientists would be split on whether there is adequate supporting experimental

evidence. Some might classify glyphosate as “Likely to be carcinogenic”; others, as “Suggestive evidence.”

7. I also believe that some ORD scientists might classify glyphosate as “Likely” on the basis of experimental data alone, by accepting positive trend tests at two anatomical sites (despite differing results in other studies) or by viewing these tumors (which not everyone accepts) as rare.

8. The remaining EPA category (Inadequate information) has not been discussed within ORD, though the positive (albeit “limited”) association in the human studies would seem to rule this out.

9. Bottom line: Based on glyphosate discussions to date among ORD scientists—where we have not formally discussed a classification—I believe we would be split between “Likely to be carcinogenic” and “Suggestive evidence.”

From: McQueen, Jacqueline

Sent: Friday, December 04, 2015 7:49 AM

To: Cogliano, Vincent <cogliano.vincent@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>

Cc: Fegley, Robert <Fegley.Robert@epa.gov>

Subject: Fw: Glyphosate follow up

Good morning. See below for the next steps on glyphosate. OPP is anxious to see ORD's specific comments, so they can begin working on them. Please take a look at Tom's action items below and let me know if the table is ready to share. Also, can you draft the short summary of ORD's conclusions, and provide the summary of the cancer guidelines that was used at the briefing for Tom?

We'd like to get these over to OPP as soon as possible. Once I get the materials from NCEA, we can circle back to make sure that Tom is ok with the the whole package.

Thanks in advance, and please let me know if we need to discuss.

Jackie McQueen

From: Deener, Kathleen
Sent: Thursday, December 3, 2015 5:45 PM
To: McQueen, Jacqueline
Cc: Hauchman, Fred; Fegley, Robert; Gwinn, Maureen; Bahadori, Tina
Subject: Glyphosate follow up

Hi Jackie –

Nice to run into you today in the food court! I talked with Tom about glyphosate, and here are the next steps:

- Review the four column chart and make sure it's good to send over to OCSPP (Tom wants them to have that, and he wants to use the 4-column version)
- Develop a one-pager that briefly (1-2 paragraphs) describes ORD's conclusions – including where we believe the cancer guidelines would lead us given this data set.
- At the meeting, Vince also had a hand-out of the cancer guideline categories. I can pull this from the Cancer Guidelines document, but it looks like he had a nice summary version. It would be great if NCEA would share that.

Thanks! Give me a call if you want to talk about any of this. I'll assume OSP will do the coordinating on this unless I hear otherwise from you.

Kacee Deener, MPH

Senior Science Advisor

Office of Research and Development

(ph) 202.564.1990 | (mobile) 202.510.1490

deener.kathleen@epa.gov

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